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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/654,373	09/01/2000	Sean C Semple	INEX.P-007	5857

21121 7590 04/23/2002

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EXAMINER
NAFF, DAVID M

ART UNIT	PAPER NUMBER
1651	9

DATE MAILED: 04/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/651373	Sengupta et al
Examiner	**Group Art Unit**
Kaufman	1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 1/10/02.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims 1-22

☒ Claim(s) _____ is/are pending in the application.

Of the above claim(s) 10-22 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-9 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6 (filed 7/11/01)

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

The application is a continuation-in-part of application 09/078,954, now Patent No. 6,287,591.

In a response of 1/10/02 to a restriction requirement of 12/10/01, applicants elected the Group I claims 1-9 without traverse, and included a corrected drawing for Figure 18.

Claims 10-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8 (filed 1/10/02).

Claims examined on the merits are 1-9 which are all claims in the application.

Needham et al and Thierry et al (Nucl. Acids Res.) listed on form PTO-1449 have been lined through since copies did not accompany the form.

The disclosure is objected to because of the following informalities: the specification fails to define the abbreviation "DOPE".

Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear by (b) of claim 1 being unclear as to the meaning of "ODNs", and not having clear antecedent basis for

the lumen or interlamellar spaces". Additionally, in (a) of the claim, steric barrier lipid" is uncertain as to meaning and scope.

In claims 5, 6, 8 and 9, the complete name rather than abbreviations should be used to for the claims to be clear as to the materials required.

Claim 8 is confusing and unclear by the specification not defining the abbreviation "DOPE".

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wheeler et al (WO 96/40964).

The claims are drawn to oligodeoxynucleotide-containing lipid vesicles in an aqueous carrier wherein a portion of the vesicles are

multilamellar vesicles containing 20-30% ionizable amino lipid, a steric barrier lipid and neutral or sterols and ODNs in the lumen or interlamellar spaces of the multilamellar vesicles.

Wheeler et al disclose encapsulating a therapeutic agent such as antisense oligonucleotides or ribozymes (page 17, lines 14-15) in a lipid bilayer (page 23, lines 3-15, and page 26, line 23) prepared from cationic and non-cationic lipids (page 4, lines 2-7, and page 26, line 17) to provide lipid particles of about 50-150 nm in size containing encapsulated nucleic acid. The cationic lipid is an amino lipid (page 15, line 16) and the non-cationic lipid may be polyethylene glycol conjugated to ceramides such as PEG-CerC14 (page 25, lines 17-20, and Table 1 (page 53) and Table 2 (page 54)). As shown in the tables, lipid mixtures containing an amino lipid, a mixture of neutral lipids and a PEG-ceramide are used to encapsulate nucleic acids. The lipid encapsulated nucleic acid can be used to treat a patient by gene therapy to suppress gene expression (paragraph bridging pages 42 and 43).

The lipid particles containing encapsulated nucleic acids of Wheeler et al can be multilamellar, have the same composition and inherently have ODNs as presently claimed. It would have been obvious to put the particles in an aqueous carrier for therapeutic use.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-72 of U.S. Patent No. 6,287,591 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed composition would have been obvious from the claims of the patent drawn to nucleic acid-containing vesicles.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651

DMN
4/19/02